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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,396	12/21/2001	Danny Huylebroeck	2676-5174ÜS 3530 EXAMINER	
24247	7590 10/23/200	3		
TRASK BRITT			RAWLINGS, STEPHEN L	
P.O. BOX 2550 SALT LAKE CITY, UT 84110			ART UNIT	PAPER NUMBER
	•		1642	11
			DATE MAILED: 10/23/2003	1/

Please find below and/or attached an Office communication concerning this application or proceeding.

,	Application No.	Applicant(s)				
	10/028,396	HUYLEBROECK ET AL.				
Office Action Summary	Examin r	Art Unit				
<b></b>						
Stephen L. Rawlings, Ph.D. 1642 The MAILING DATE of this communication appears on the cover sheet with the correspondenc address						
Period f r Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status						
1) Responsive to communication(s) filed on <u>03 June 2002</u> .						
2a) This action is <b>FINAL</b> . 2b) This action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>						
4)⊠ Claim(s) <u>1-17</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) 1-17 are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
Copies of the certified copies of the priority documents have been received in this National Stage     application from the International Bureau (PCT Rule 17.2(a)).      *See the attached detailed Office action for a list of the certified copies not received.						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) 🔲 The translation of the foreign language provisional application has been received.						
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)				

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## DETAILED-ACTION-

1. The amendment filed December 21, 2001 is acknowledged and has been entered. Claims 3, 4, 6, 10, and 12 have been amended.

- 2. The amendment filed June 3, 2002 is acknowledged and has been entered. Claims 1, 2, 7, and 13-17 have been amended.
- 3. Claims 1-17 are pending in the application and are currently subject to the following restriction.

## Election/Restrictions

- 4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Groups I-IV. Claims 1-6, insofar as the claims are a process for identifying transcription factors and a transcription factor identified by said process, wherein said process comprises providing cells with a nucleic acid sequence comprising one of the sequence selected from the group consisting of CACCTNCACCT, CACCTNAGGTG, AGGTGNCACCT, and AGGTGNAGGTG, classified in class 435, subclass 4+ and 530, subclass 350.

Note: Claim 1 will be withdrawn from consideration if Applicant elects the invention of group IV, claims 2-6, insofar as the claims are drawn to a process for identifying transcription factors and a transcription factor identified by said process, wherein said process comprises providing cells with a nucleic acid sequence comprising AGGTGNAGGTG.

Groups V-VIII. Claims 7-11, insofar as the claims are drawn to a method for identifying compounds with an interference capability towards transcription

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-factors, wherein-said-method-comprises-adding-a-sample-to-a-test-system-comprising a nucleotide sequence selected from the group consisting of CACCTNCACCT, CACCTNAGGTG, AGGTGNCACCT, and AGGTGNAGTG, classified in class 435, subclass 6.

- Group IX. Claim 12, drawn to a pharmaceutical composition comprising a compound, which cannot be classified because the chemical and biologic nature of the compound has not been specified.
- Groups X-XIII. Claim 13, 14, and 16, insofar as the claims are drawn to a nucleic acid molecule comprising a polynucleotide sequence selected from the group consisting of CACCTNCACCT, CACCTNAGGTG, AGGTGNCACCT, and AGGTGNAGTG, and a kit comprising said nucleic acid molecule, classified in class 536, subclass 23.1.
- Groups XIV-XVII. Claim 15, insofar as the claim is drawn to a method for detecting an interaction between a first interacting protein and a second interacting protein, wherein said method comprises providing a host cell with a fusion protein comprising a first interacting protein fused to a DNA binding domain capable of binding a nucleic acid molecule comprising a sequence selected from the group consisting of CACCTNCACCT, CACCTNAGGTG, AGGTGNCACCT, and AGGTGNAGTG, classified in class 435, subclass 373.
- Groups XVIII-XXI. Claim 17, insofar as the claim is drawn to a method for identifying a new target gene, wherein said method comprises using a nucleic acid molecule comprising a sequence selected from the group consisting of CACCTNCACCT, CACCTNAGGTG, AGGTGNCACCT, and AGGTGNAGTG, classified in class 435, subclass 6.

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5. The inventions are distinct, each from the other because of the following reasons:

The inventions in groups IX-XIII are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods, and therefore the claimed products are distinct.

The inventions in groups I-VIII and XIV-XXI are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success, and therefore the claimed methods are distinct.

Inventions in groups X-XIII and groups I-VIII and XVIII-XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed, namely nucleic acid molecule can be used in a materially different process of using that product, such as the process of determining the presence of a second nucleic acid molecule in a sample, wherein said second nucleic acid molecule hybridizes to the claimed nucleic acid molecule.

The inventions in group IX and groups I-VIII and XIV-XXI are not at all related because the products of group IX are not specifically used in any of the steps of the claimed methods in groups I-VIII and XIV-XXI.

The inventions in groups X-XIII and groups XIV-XVII are not at all related because the products of groups X-XIII are not specifically used in any of the steps of the claimed methods in groups XIV-XVII.

6. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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-7. Applicant\_is\_advised\_that\_the\_reply\_to\_this\_requirement\_to\_be\_complete\_must-include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Claim 1 is a linking claim, linking the inventions of claim 2, insofar as the claim is drawn to a process for identifying transcription factors and a transcription factor identified by said process, wherein said process comprises providing cells with a nucleic acid sequence comprising one of the sequence selected from the group consisting of CACCTNCACCT, CACCTNAGGTG, and AGGTGNCACCT.

The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

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-whichever-is-earlier.—Amendments-submitted-after-final-rejection-are-governed-by-37-CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is

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-(703)-305-3008.—The-examiner-can-normally-be-reached-on-Monday-Friday,-8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

1 Konl OTEPHEN RANLINGS

Stephen L. Rawlings, Ph.D. Examiner
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slr October 20, 2003